US ERA ARCHIVE DOCUMENT

July 14, 1983

Subject: BPA File Symbol 538-RIL

Proturf Pythium Control

Deloris P. Graham DSH 7 20 83 PHB/TSS

Henry Jacoby

Product Manager (21)

Applicant: 0. M. Scott & Sons Company

Attn: Michael P. Kelty Marysville, Ohio

Active Ingredient:

Metalaxyl M-(2,6-Dimetr / .. .enyl)-N-(2,6-Dimethylphenyl) = aethoxyacetyl) alanine, methyl ester ......

Inert Ingredients.....

Background: Submitted Acute Oral, Acute Dermal, Eye Irritation and Primary Skin Irritation Studies. Studies conducted by Hazleton Raltech, Inc. Data under Accession Number 249999. Alternate Method of Support used.

## Recommendation:

- 1. TSB/TSS finds these data acceptable to support conditional registration of this product.
- 2. An Acute Inhalation Study was not submitted and one must be submitted and/or cited or a justification as to why this study is not necessary.
- 3. The appropriate signal word is CAUTION.

## Label:

1. The statement \*Do not contaminate feed or foodstuffs. Do not feed clippings to livestock. Keep children and pets off treated area until material has been washed off the foliage and the area is completely cry\* must be deleted from precautionary statements and placed under the heading Directions for Use.

## Review:

Acute Oral Toxicity Study: Hazleton Raltech, Inc.; Lab. #730974; Jaguary 20, 1983.

Procedure: 5M and 5F Sprague-Dawley rats weighing between 200 and 289 g received 5 g/kg of the test material orally. Observations were made for 14 days after treatment. Mecropsy performed on all animals.

Results: No mortalities. Toxic signs observed include diarrhea, brown stained anal area. Mecropsy revealed lungs - diffuse, pinpoint, gray foci on all lobes, small-raised area on right caudal lobe, dark red with white center; liver - liver-like protrusion, spherical in shape, achered to diaphragm; thymus - reddened on right side. LD50 greater than 5.0 g/kg.

Study Classification: Core Guideline Data

Toxicity Category: IV - CAUTION

2. Acute Dermal Toxicity Study: Hazleton Raltech, Inc.; Lab. #730974;
January 20, 1983.

Procedure: Pive male and five female New Zealand rabbits weighing between 2573 and 2926 grams received 2 g/kg of the test material at abraded skin sites under occlusive wrap for 24 hour exposure. Observations were made daily for 14 days after treatment. Necropsy performed on all animals.

Results: No mortalities. Brythema, edema, atomia, desquamation, fissuring and coriaceousness noted. No other toxic signs noted. Hecropsy revealed treated skin crusty; left salivary gland reddened. LD50 greater than 2 g/kg.

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

3. Skin Irritation Study: Hazleton Raltech, Inc.; Lab. #730974; January 10, 1983.

Procedure: Six New Zealand rabbits received 0.5 g of the test material on two abraded and two intact skin sites per animal under occlusive wrap for 24 hour exposure. Observations were made at 24 and 72 hours after treatment.

Results: At 24 hours, 6/6 slight to well defined erythema (scores of 1, 1.5 and 2.0) and slight to well defined edema (scores of 1, 1.5 and 2.0). At 72 hours, 6/6 had slight to well defined erythema (scores of 1, 1.5 and 2.0) and 4/6 slight edema (score of 1). Dermal Irritation Score = 1.3.

Study Classification: Core Guideline Data

Toxicity Category: IV - CAUTION

4. Eye Irritation Study: Hazleton Raltech, Inc.; Lab. #730974; January 13,

Procedure: Nine New Zealand rabbits received 0.1 g of the test material in one eye each. The treated eyes of three of the rabbits were washed with lukewarm water 30 seconds after treatment. Observations were made at 24, 48, 72 and 96 hours and at 7 days after treatment.

Results: At 24 hours, 4/6 animals of the unwashed group had corneal opacity (2/6-5, 1/6-10, 1/6-11.25) and no corneal opacity in 3/3 animals of the washed group; 5/6 iris irritation (5/6-5); 6/6 and 3/3 conjunctive redness (1/6-1, 5/6-3)(1/3-1.5, 2/3-2); 5/6 chemosis (2/6-2, 3/6-3); 5/6 and 1/3 discharge (2/6-1, 1/6-1.5, 2/6-2.5)(1/3-1).

At 96 hours, 1/6 corneal opacity (1/6=11.25); 5/6 and 1/3 conjunctive redness (4/6=1, 1/6=2)(1/3=1); 2/6 chemosis (1/6=1, 1/6=1.5) and 1/6 discharge (1/6=1).

At 7 days, corneal opacity and all other irritation had cleared.

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

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